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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,114	07/03/2007	Ludger Grote	C2432.0069	1212

32172 7590 11/28/2008

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,114	GROTE ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,22,24 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,22,24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/09/2007. Claim(s) 1-13, 22, 24, and 26 are pending and are examined herein.

Response to Arguments

Applicant's arguments with respect to the 112-1st paragraph rejection of claim 24 have been considered, the rejection is hereby withdrawn.

Applicant's arguments with respect to the 103(a) rejection of claims 1-13, 22, 24, and 26 as being unpatentable over Hedner et al. (WO 01/62243A1) in view of LaRoche et al. (JAMA, 2004) has been fully considered but is not persuasive.

In response to Applicant's comment regarding the WO reference employed in the 103 rejection, Examiner is fully aware that the WO reference is the same inventor as in the instant application. Nonetheless, because the priory date, for art purposes, of this application is 2/17/2004, this reference qualifies as a "102b-type" date reference that can be employed in a 103 rejection. As Applicant is aware, because the publication date of the WO document is more than one year prior to the claimed priority date of the instant application, whether or not the inventor is the same is irrelevant.

Applicant argues the fact that two compounds, of which are antiepileptic (or other), and lack a common structural element cannot be predicted from their structure to be able to treat common ailments. Further, Applicants have submitted data from a

clinical study involving 4 patients to compare the effectiveness of treating sleep apnea with zonisamide and topiramate.

Examiner respectfully notes that because both topiramate and zonisamide are known to be antepileptic agents and the fact that they have common mechanisms of action would motivate one of ordinary skill in the art to try with a reasonable degree success in the absence of unexpected results to employ one anticonvulsant over another for treating sleep apnea. The clinical data provided by Applicant has been fully considered but is not persuasive. The results presented are not "unexpected results" per se because Applicant has further confirmed that topiramate is also effective in reducing apnea (50% effective versus 75% effective over zonisamide). The fact that only one patient responds to both therapies is not surprising because the doses of topiramate and zonisamide are different. Furthermore, although Applicant provides references indicating that there are some anticonvulsants that would not be effective in treating apnea, it is not the Examiner's contention that all anticonvulsants will be effective in reducing sleep apnea. It is Examiner's contention that it would be obvious to try known anticonvulsants, with comparable mechanisms of action, with a reasonable degree of success that if one anticonvulsant is successful, then so could another.

The 103(a) rejection is maintained and has been restated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedner et al. (WO 01/62243 A1) in view of LaRoche et al. (*JAMA*, 2004).

Hedner teaches a method of treating snoring, sleep apnea and other forms of sleep disorder breathing, all of which are encompassed by the term OSA (obstructive

sleep apnea), with the administration of topiramate, a compound licensed to treat epilepsy (page 3, line 35-page 4, line 6; claim 1).

Hedner makes no mention of any of the sleep orders arising as a result of external mechanical obstructions, such as mucus.

Hedner teaches that an effective dose of topiramate is one which eliminates or substantially reduces the manifestations of OSA-related conditions over a period of sleep, such as sleep periods from 10 minutes to 10 hours (page 6, lines 19-22; claims 2-5).

Further Hedner teaches that topiramate can be administered by various routes, including peroral administration or the compound may be incorporated in tablets, lozenges, capsules (page 6, lines 26-31; claim 6) in addition to parenteral, intranasal, rectal as well as transdermal (page 7, lines 29-32).

Furthermore, Hedner teaches that the dose range for peroral administration of topiramate is in the interval from 10 to 1000 mg per 24 hours, wherein 50% or more is released within a period of three hours (claim 8, 13) and 80% or more within a five hour period (claim 9, 14).

Hedner teaches a protective patch comprising of topiramate in an effective amount to treat sleep disordered breathing including sleep apnea (page 7, line 29-page 8, line 4; claim 17).

Hedner further teaches that topiramate may also be combined with other pharmacologically active compounds useful in the treatment of OSA (page 8, lines 16-20).

Hednar does not teach zonisamide, also an antiepileptic drug, as the active agent.

LaRoche teaches that both topiramate and zonisamide are broad-spectrum anticonvulsants and act by way of blocking sodium as well as T-type calcium channels (page 607, see figure).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the anticonvulsant agent, topiramate, as taught by Hedner to treat OSA, with zonisamide, as taught by LaRoche. One would expect with a reasonable degree of success that because both agents are used to treat epilepsy and have similar modes of action as taught by LaRoche and thus would expect that substitution of one agent over the other to be reasonably successful in the absence of unexpected results.

Conclusion

Claims 1-13, 22, 24, and 26 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617